DGHT
Division of Global HIV & TB

ESTABLISHING SYSTEMS AND IMPROVING EFFICIENCIES FOR ENHANCING EQUITABLE ACCESS TO TESTING SERVICES AND UPTAKE OF TEST RESULTS

OVERVIEW

Reliable laboratory systems are critical to the delivery of quality healthcare services. Establishing and improving laboratory systems for HIV and Tuberculosis (TB) provides platforms that enable countries to better respond to other diseases. The sustainability of these systems is key to ensure perpetual readiness of laboratory diagnostics services, surveillance, and outbreak investigations.

The U.S. Centers for Disease Control and Prevention's (CDC's) International Laboratory Branch (ILB) provides technical expertise to priority countries supported by U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and CDC's Global TB program to effectively reach UNAIDS' "90-90-90" targets, the World Health Organization's (WHO) "End TB Strategy", and the Stop TB Partnership's "Global Plan to End TB" targets. CDC's strategic approach to HIV and TB epidemic control is to develop and strengthen existing laboratory capacities, improve efficiencies, and strengthen a country's capacity for robust health services delivery.

HIV VIRAL LOAD TESTING

To support patient management, CDC's strategy is to establish systems and improve efficiencies for viral load testing and uptake of test results.

As part of this strategy, CDC is:

- Deploying tools (Clinician and Laboratory Training, Specimen Referral Guidance, Costing, Forecasting, and Monitoring and Evaluation);
- Supporting regional activities to train in-country personnel on the tools;
- Convening regional workshops for strategic planning and tool dissemination;
- Engaging existing and new implementing partners for additional in-country support; and
- Developing and deploying the Viral Load (VL)/Early Infant Diagnosis laboratory scorecard.

Specific CDC activities include:

- Supporting countries with workflow optimization for plasma and dried blood spot (DBS) testing;
- Clearing viral load sample backlogs;
- Mapping laboratories to clinical sites for more efficient sample referral;
- Working with manufacturers to optimize platform procurement and maintenance;
- Providing remote and in-country technical assistance and monitoring and evaluation support; and
- Piloting laboratory scorecards.

These efforts and activities contribute to effective virologic monitoring for patients in antiretroviral treatment (ART), informed adherence counseling and treatment changes for patients failing treatment, and improved efficiencies throughout the entire clinical and treatment spectrum.

BUILDING LABORATORY INSTITUTIONAL CAPACITY AND LEADERSHIP

The laboratory academic partnership with Georgia State University's School of Public Health and Andrew Young School of Policy Studies – Muhimbili University of Health and Allied Sciences (GSU-MUHAS) provides state-of-the-art curriculum content and instructional design, along with cutting edge approaches for course delivery in sub-Saharan Africa. The goal of the partnership is to expand training opportunities to laboratory professionals in Tanzania and other East African countries. This collaboration builds upon and expands MUHAS's prior World Bank-supported laboratory training investments, with an added focus of sustaining institutional capacity beyond the scope of this project. Activities include reciprocal site visits between faculty at each institution; convening a GSU-MUHAS satellite meeting in tandem with the African Society for Laboratory Medicine; and reviewing and conducting a gap analysis of the current MUHAS curriculum with suggestions for courses enhancement and hybridization. Suggested revisions will include case-based analyses that incorporate essential aspects of HIV

laboratory testing, including VL testing, that advance global goals to end the HIV epidemic.

QUALITY MANAGEMENT SYSTEMS AND BIOSAFETY

Since 2007, CDC's International Lab Branch has been a College of American Pathologists accredited laboratory. CDC supports countries in the development of laboratory quality management systems. We also provide technical assistance to Ministries of Health as they pursue continuous quality improvement (CQI) programs consistent with recognized quality standards. CDC has assisted more than 12 laboratories in attaining internationally recognized laboratory accreditation to ISO standards. CDC's International Lab Branch is one of five laboratory branches at CDC participating in an ISO 17025 external accreditation pilot project. External accreditation is a tool to catalyze the full implementation of quality management systems. Lessons learned from the pilot project will guide over 60 CDC laboratory branches on the path toward external accreditation.

Biosafety in point of care and laboratory settings is essential, not only to the diagnosis (testing), care, and treatment of patients, but to safeguard laboratorians, providers, and other workers against potential infectious exposures in healthcare and laboratory facilities. It is important that the necessary safety measures are in place to ensure that hazardous material and potentially dangerous pathogens are safely handled, stored, and disposed. CDC provides biosafety technical assistance to evaluate laboratory and healthcare facilities on safe practices, procedures, and systems, and provides biosafety training and mentoring to laboratory and healthcare professionals.

PUBLIC PRIVATE PARTNERSHIPS

Recognizing that laboratories face challenges globally to keep pace with scaling up care and treatment activities, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and CDC have built strategic public-private partnerships with shared resources for laboratory strengthening with three private companies that support global HIV goals in sub-Saharan Africa and Asia. Leveraging resources from the private sector to support the public sector helps promote long-lasting impact of a country's response to the HIV epidemic in the areas of quality improvement, accreditation, sample referral and training programs. These partnerships include: Labs for Life with Becton Dickinson (BD), Stronger Together with Siemens Healthineers, and the Roche Diagnostics-PEPFAR public-private partnership.

EXTERNAL QUALITY ASSESSMENT

CDC has adapted the dried tube specimen (DTS) technology, originally developed for serology quality assurance (QA), for VL testing external quality assessment activities. External performance assessment is one of the key elements to ensuring the quality of laboratory testing. Liquid plasma specimens for EQA require high costs to maintain cold chain transportation, but DTS are non-infectious and stable at ambient temperature for up to 8 weeks. As such, DTS panels do not require special shipping, have lower shipping costs, and can be tested on existing polymerase chain reaction-based HIV-1 RNA VL testing platforms. DTS can be used for split sample testing and provides an avenue for VL testing laboratories in PEPFAR-supported countries to monitor and evaluate their VL testing service quality.

Data indicate that laboratories participating in external performance assessment programs for longer periods of time achieve overall higher performance scores, which may translate into better and more accurate VL monitoring, and as a result – improved treatment and patient outcomes. In October 2015, a survey was conducted among 159 laboratories in 43 countries that participated in CDC quality assurance and performance assessment programs. Of the 123 responding laboratories, 92 percent self-reported that participation in the CDC quality assurance and performance assessment programs improved the quality of HIV molecular testing. A monthly average of 86,325 VL tests were performed by 491 staff members across all of the laboratories.

CDC is also adapting this DTS technology for point of care infant virological testing (IVT) quality assurance. There are currently two World Health Organization prequalified technologies, Alere q HIV-1/2 Detect and Xpert HIV-1 Qual, for POC IVT. Implementation studies are beginning with deployment of new technologies. As these and other new point of care technologies are scaled and placed in more decentralized settings, parallel quality assurance tools will be essential to ensure the accuracy of the testing. With DTS used to assess the quality of conventional VL and rapid diagnostic testing, DTS for point of care IVT aims to mimic patient specimens and the workflow closely – allowing for assessment of operator proficiency and certification of testing sites.

ENHANCING ACCESS TO QUALITY TB DIAGNOSTIC SERVICES

Insufficient TB laboratory capacity and quality management limit universal access to accurate and reliable TB diagnostic services. To improve patient access to quality TB testing services in resource-limited settings, CDC developed a CDC/FIND Xpert MTB/RIF CQI Manual to assess and strengthen national Xpert MTB/RIF rapid diagnostic and drug susceptibility testing networks. A CDC/ASM Mentor4TB Program is providing TB laboratories with a long-term, structured mentorship framework for human resource and quality management capacity building. CDC is piloting these efforts. In addition, CDC is supporting the establishment and expansion of external quality assessment for TB testing facilities by delivering DTS-based Xpert MTB/RIF proficiency testing material to 565 sites in 26 countries, transferring the Xpert MTB/RIF PT program to partner countries in a stepwise and supported manner, and providing customized technical assistance to more than 30 countries on CQI of national TB diagnostic policies and network strengthening.

SPOTLIGHT:DRIED BLOOD SPOT FOR HIV VIRAL LOAD TESTING

As more people are identified as HIV-positive and receive antiretroviral treatment, there is an urgent need to monitor patients on treatment. VL testing measures the amount of HIV virus in the blood and can be used to monitor the effectiveness of treatment.

VL testing typically requires fresh whole blood plasma specimens, which can be challenging to transport and store in many resource-limited settings. CDC is leading research to use dried blood spot technology for VL testing and is investigating the use of point-of-care VL test technologies in these same settings.